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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,789	02/12/2002	Todd R. Golub	WIBL-P02-518	8072
28120	7590	01/26/2005	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			MORAN, MARJORIE A	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

10/074,789

Applicant(s)

GOLUB ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 and 65-71 is/are pending in the application.
- 4a) Of the above claim(s) 65-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/9/04</u> . | 6) <input type="checkbox"/> Other: _____  |

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All rejections and objections not reiterated below are hereby withdrawn.

***Election/Restrictions***

Claims 65-70 are again withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response filed 1/20/04.

An action on the merits of elected claims 1-14 and 71, as they read on the elected species, follows.

***Information Disclosure Statement***

The information disclosure statement filed 9/9/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but all the information referred to therein has not been fully considered. References AU4, by Pennisi, E., and AW4, by Gordon, A.D. have not been received. It is noted that several references not listed on the IDS were received with those which are listed on the IDS. Thus, although the number of documents received by the PTO may match the number sent, acknowledgment of receipt of a number of documents by the PTO is not confirmation that the documents listed on the PTO have been received. Further, as it is unclear whether applicant wished the "extra" documents to be made of record and considered, they have not been

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listed on a PTO Form 892.

References previously considered have been crossed out to avoid duplication upon printing. Reference AV5 by Eisen et al. is identical to reference Av on page 1 of the lds, and has also been crossed out to avoid duplication. Reference AV has been considered.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission of that item for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

### ***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See e.g. page 47. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Amended claim 7 recites genes encoding expression products, which is new matter. Original claim 7 recited informative genes selected from a group, wherein the listed group comprised protein names. It was noted in the previous office action that the claim was indefinite, and that if applicant intended the gene to be one which *encodes* one of the recited proteins, the rejection may be overcome by clearly reciting applicant's intent. Applicant was specifically reminded that any amendment to the claims must be fully supported and enabled by the originally filed disclosure. The original claims did not recite encoding language anywhere. The original specification, on page 5, discloses that "informative genes can be, for example" and lists the same protein names as those of original claim 7. Page 5 does not disclose genes *which encode* the listed proteins. In the response filed 9/9/04, applicant points to pages 6, 21, and 47 of the specification for support for the new limitation of claim 7. Pages 6 and 21 merely disclose the term "gene expression" and "gene expression products" but do not provide specific support for genes encoding the proteins listed in claim 7. Page 47 discloses that many genes useful in ALL-AML class prediction encode particular proteins. The proteins disclosed as being encoded by genes in lines

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22-24 are a small subset of those recited in claim 7. Thus, the originally filed specification does not provide support for genes encoding all of the proteins listed in claim 7; for example, proteosome iota, MB-a, myosin light chain, and inducible protein. It is noted that this list is EXEMPLARY, and that many other proteins are listed in claim 7 which also lack support with regard to encoding genes. As neither the originally filed specification or claims provide support for genes encoding many of the proteins recited in amended claim 7, claim 7 recited new matter and is rejected.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites "the one or more classes" in lines 6. There is insufficient antecedent basis for this phrase in the claims, therefore claim 9 is indefinite. If applicant intends one or more informative genes, then this rejection may be overcome by inserting the term "informative" before "genes" in each recitation of the phrase.

Claim 10 recites the limitations "the first class" and "the second class in the last two lines. There is insufficient antecedent basis for these limitations in the claim, therefore the claim is indefinite. Applicant has not amended these

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terms nor amended the claims elsewhere to provide antecedent basis, nor presented arguments to overcome this rejection, therefore the rejection is maintained.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over ZHENG et al. IEEE Transactions on Neural Networks, (11/1997) vol. 8 (6), pp. 1386-1396) in view of EISEN et al. (IDS ref AV: PNAS

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(12/1998) vol. 95, pp. 14863-14868) and TAMAYO et al. (IDS ref AX2: PNAS (3/1999) vol. 96, pp. 2907-1912).

ZHENG teaches a method of classifying malignant vs. benign breast tissue using weight adjustments (i.e. a weighted "voting" scheme), summation of votes and use of a prediction threshold (confidence level) to determine a winning class (pp. 1389-1390). ZHENG does not teach use of informative genes, classification of leukemia nor use of a statistical routine. ZHENG does not specifically teach a clustering routine.

EISEN teaches a method of clustering genes using a Euclidean routine to determine similarity (p. 14863). EISEN teaches that weighting may be used to order his genes (p. 14864), and teaches clustering of genes encoding many of the same proteins listed in instant claim 7 (Figure 2).

TAMAYO teaches cluster analysis of gene expression patterns involved in leukemia (abstract and page 2910). TAMAYO also teaches that clustering analysis may include Bayesian clustering (p. 2907).

It would have been obvious to one of ordinary skill in the art to have combined ZHENG's weighted voting scheme, summation of votes, and confidence level threshold/cutoff with EISEN's or TAMAYO's Euclidean routines to cluster and classify genes involved in cancer, specifically the leukemia of TAMAYO, where the motivation would have been to organize data in manner intuitive for biologists, as taught by EISEN (abstract) and to highlight genes and pathways involved in differentiation and cancer "therapy," as taught by TAMAYO (abstract). One skilled in the art would reasonably have expected success in



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combining the classification method of ZHENG with the classification of gene expression data of ESEIN and TAMAYO because all teach similar statistical methods of clustering and classification of biological/array data.

### ***Conclusion***

No claims are allowed.

The art made of record and not relied upon which is considered pertinent to applicant's disclosure is: GOLUB et al. (Science (10/15/1999) volume 286, pages 531-537).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran  
Primary Examiner  
Art Unit 1631

*Marjorie A. Moran*  
11/24/05